Amendments to Drawings:

Please replace Figures 1-3 with amended Figures 1-3 attached hereto, and add new FIG 4 attached hereto.

REMARKS

By this amendment, Applicant has provided a Substitute Specification and has amended the claims in an effort to fully respond to all the issues raised by the Examiner. All of the amendments to the application are supported in the original specification, and no new matter has been entered. Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Information Disclosure Statement:

In response to the Examiner's objections regarding Applicants' Information Disclosure Statement (IDS), Applicant submits herewith a concise explanation of why that portion is relevant. With regard to the translation of the Demling et al. reference, the regulations provide that the IDS shall include any information known to be material to patentability including each cited publication or that portion that caused to be listed or even that portion of the document that is considered by the applicant to be pertinent to the application, together with a concise explanation of why that portion is relevant, as it is presently understood by the applicant. Non-English-language documents, or portions thereof, should be filed with a copy of a written English-language translation. Applicants have complied with these regulations, and further inform the examiner that the pertinent part of the Demling et al. reference is the Abstract, to which a translation is present on the front page of the document filed with the Information Disclosure Statement filed August 8, 2008. To the extent that a further concise explanation of why that portion is relevant is required, Applicants submit the information below:

Concise explanation of relevance: Applicants note that the Demling et al. reference defines the general state of art that is not considered to be of particular relevance and is cited in the present invention as a prior art document merely describing a general and known process in the field of catheters, endoscopic papillotomy and removal of gallstones in animal experiments. The reference shows some initial clinical results and the abstract explains that Animal experiments have demonstrated that satisfactory papillotomy can be carried out with a high-frequency diathermy catheter.

Drawings:

In response to the Examiner's objections to the drawings, and without addressing the merits of the Examiner's position, the Drawings have now been amended in response to the Examiner's request, and all drawing figures now include reference character A. In addition, pursuant to the Examiner's request, the guiding line is now clearly represented in New Figure 4. Regarding the second external concentric tube having a first extremity attached to the manipulation component, Applicant respectfully submits that reference character (3) clearly represents a tube which is externally concentric to the perforating tube (4), inserted inside the second external concentric tube (7) and blockage component (8), ending at the manipulation component (2), to which it is attached. Regarding the second external concentric tube having reinforcements, Applicant has amended the claims and specification to correctly identify as the second external concentric tube having reinforcements.

Specification:

In accordance with the Examiner's request, the Abstract has been amended and is now in accordance with MPEP § 608.01 (b). In addition, pursuant to the Examiner's request, the Specification has been amended by virtue of the attached substitute specification to be in proper idiomatic English, to better describe the present invention, and to introduce statements of invention in direct agreement with the amended claims, providing proper antecedent basis for the claimed subject matter. The Specification now correctly refers to Figure 3 as the Figure showing the non-exposure of the needle. The Specification and Title have been amended to replace the term "artifon catheter" with the term "catheter". In all cases, no new matter has been added

Claim Objections:

In response to the Examiner's claim objections, Claims 9-24 have been amended to correct all informalities. Claim 15 has been cancelled, and the term "the guiding line" in Claim 24 has now correct antecedents. The term "composed" has been deleted in Claim 13. Claims have been amended to replace the term "artifon catheter" with the term "catheter".

Claim Rejections – 35 USC 112

The objection to Claim 15 has become moot in light of the cancellation of that claim

Claim Rejections under 35 USC 103(a):

In the Official Action, Claims 9-13, 19-21 and 22-24 were rejected by the Examiner as obvious over of US 5,483,091 to Holsinger et al. in view of US 6,482,171 to Andrews et al. Applicant has amended Claim 9 to introduce the limitations of Claims 14 and 15 into independent Claim 9. As indicated in the Office Action, the limitations of Claims 14 and 15 are not found in neither Holsinger et al. nor Andrews et al., thus distinctly differentiating amended independent Claim 9 from the both prior art cited.

Additionally, the Examiner alleges that character 208 in Figure 6A in Holsinger et al.represents an external concentric tube. Applicant draws the Examiner's attention to Column 12 line 66 to Column 13 line 03, where Holsinger et al. clearly describes "*Turning now to FIGS. 6 and 6A, there is shown a top, plan view of an actuation assembly, generally indicated at 200, for a controlling extension of an injection needle 204 from the distal end 208b* ***of a catheter 208*** *in which the injection needle is carried.*" (Emphasis added). Accordingly, the Examiner's allegation that the catheter in Holsinger et al. comprises an external concentric tube (208), as in the present invention, is not sustainable.

Furthermore, the Examiner alleges that member 12A in Figure 1A is an external manipulation component adjacent to the manipulation component of the perforation tube. However, Holsinger et al. clearly describes in Column 6, lines 25-32 "*Referring to FIG. 1, there is shown a top plan view of a needle-knife assembly, generally indicated at 10, which is adapted for use with a multi-lumen catheter 12.* ***The multi-lumen catheter 12 has a connector 14 attached to a proximal end 12a thereof****, the connector including a*

luer lock hub 17 for attachment of the needle-knife assembly. Also present is a polymeric tube 20 which may be used for injection of a contrast medium or some other purpose". (Emphasis added). Accordingly, the examiner allegation that member 12A in Figure 1A is an external manipulation component of the catheter in Holsinger et al. is also not sustainable.

Even further, the Examiner alleges that the device in Holsinger et al. can incorporate an external locking mechanism as described in Column 12 lines 53-65 therein. However, Column 12 lines 53-65 describe "*Turning now to FIG. 5A, there is shown an end view of the extension regulator 154.* ***As was mentioned previously, the extension regulator 154 is formed by a generally C-shaped body having a plurality of protruding ribs 158 which are used to engage the grooves 152 on the body 50 of the deployment device 30****. A pair of tabs 162 extend outwardly from the C-shaped body of the extension regulator 154. Squeezing the tabs 162 together deflects the C-shaped body outwardly and enables the protruding ribs 158 to be removed easily from the grooves 152. The extension regulator 154 can then be moved to a new location and the tabs 162 released, thereby locking the extension regulator in new desired position*". (Emphasis added). The locking means in Holsinger et al. is constructed and arranged differently and also works in a different manner than the blockage means of the present invention. The generally C-shaped body engaged to the grooves of the body in Holsinger et al. is distinct from the blockage component of the present invention, which is an integral part of the manipulator. Clearly different from Holsinger et al., in the present invention, beside the manipulating function of the concentric perforating tube component, the manipulator component

presents a secondary function, which is allowing for the blockage of the exposure or retention of the needle component.

Applicant fails to comprehend on what basis and from what source the Examiner would interpret such features in a manner differently from the manner clearly described by the inventor and is respectfully submitting that is reading beyond the inventor's interpretation. Accordingly, the Examiner cannot maintain the objection to claim 9 on the basis of the features described in the office action, which are clearly distinct from the features of the present invention.

Applicant respectfully submits that Claims 10-13, 19-21 and 22-24, which depends from novel and inventive Claim 9, are submitted to patentably distinguish over the prior art and are submitted to be allowable.

Claims 14 and 15 are rejected by the Examiner as obvious over US 5,483,091 to Holsinger et al. and US 6,482,171 to Andrews et al. in view of US 6,635,047 to Forsberg. Claims 14 and 15 have been cancelled and the features of these Claims have been introduced into independent Claim 9. The Examiner alleges that Holsinger et al. do not teach the external tube having reinforcements, and that Forsberg teaches a catheter tube having a metal and polymer reinforcement layer along its length which would necessarily include the extremities in at either end. With respect to the Examiner's comments on the reinforcements disclosed in Forsberg, Applicant respectfully submits that the Examiner is not justified to assign to the Forsberg's reinforcement layer, the same features and characteristics as in the reinforcements placed on the first and second opposite extremity of the present invention. Additionally, Applicant respectfully submits that the features of

Claims 14 and 15 are now limitations of the independent Claim 9, which is believed to be novel and inventive, and is submitted to patentably distinguish over the prior art and are submitted to be allowable.

Claim 16 is rejected by the Examiner as obvious over US 5,483,091 to Holsinger et al. and US 6,482,171 to Andrews et al. in view of US 5,785,689 to Toledo; and Claims 17 and 18 as obvious over US 5,483,091 to Holsinger et al. and US 6,482,171 to Andrews et al. in view of Micley in US 2003/0216693. Applicant respectfully submits that Claims 16-18, which depends from novel and inventive Claim 9, are submitted to patentably distinguish over the prior art and are submitted to be allowable.

Accordingly, Applicants respectfully submit that all outstanding objections and rejections have been overcome and request allowance of the patent application.

In light of the foregoing, Applicants submit that the present application has been placed in condition for allowance, and such action is respectfully requested. If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicant's undersigned attorney at the Examiner's convenience.

Respectfully submitted,

Date: December 1, 2008

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